REMARKS

Status of the Claims.

Claims 45-61 and 68-76 are pending in the application, claims 62-67 and 77-86 having been cancelled in the Amendment filed on April 14, 2003 in response to the Final Rejection.

Election/Restriction Requirement.

Claims 45 and 68, the only pending independent claims, are Markush claims reciting multiple chromosomal regions. Earlier in prosecution, the Examiner identified these chromosomal regions as distinct species and required Applicants to elect one for initial examination. Applicants elected chromosomal region 17q22-24, and the Examiner examined the claims with respect to this region.

Election of species practice relating to Markush claims is governed by M.P.E.P § 803.02, which states:

> This subsection deals with ***Markush-type generic claims*** which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language.

(Emphasis added.) Applicants respectfully point out that claims 45 and 68 are Markush-type generic claims that read on the elected species, chromosomal region 17q22-q24.

Section 803.02 states:

> ***Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection***, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, ***the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim***.

(Emphasis added.) In the present application, in response to the rejection of Markush-type claims, Applicants have overcome an obviousness-type double patenting rejection by filing a Terminal Disclaimer and have overcome a § 103 rejection by pointing out that the references do not teach or suggest an amplification at 17q22-24 (see below). Therefore, Markush-type claims 45 and 68 must be reexaminined, and the prior art search must be extended to the extent necessary to determine the patentability of these claims. Applicants submit that § 803.02 requires the Examiner to examine at least one additional species recited in these claims. If the Examiner is able to make a proper art-

based rejection of this additional species, the Examiner need not go on to examine any other species. If the Examiner is not able to make such a rejection, the Examiner must go on to examine another additional species. Examination of the Markush claims must continue until the Examiner encounters a species that can properly be rejected over prior art or the Markush claims are fully examined. Accordingly, Applicants respectfully request examination of one or more of the additional species recited in claims 45 and 68, in compliance with § 803.02.

35 U.S.C. § 103(a).

Claims 68-71 and 74-76 were rejected under 35 U.S.C. § 103(a) as allegedly obvious in light of Alitalo (Proc. Natl. Acad. Sci. USA(1983) 80:1707-11) in view of Hainsworth *et al.* (Cancer Genet. Cytogenet. (1991) 53:205-18). Final Office Action, page 3. This rejection is respectfully traversed.

Of the rejected claims, only claim 68 is independent. Claim 68 relates to a "method for detecting a copy number variation in a suspected breast cancer sample by detecting an amplification or gain of unique sequences at" positions including q22-q24 on chromosome 17. Detection is carried out by hybridizing a suitable probe to the sample and detecting the hybridization complex.

The Examiner stated that "Alitalo teaches a method for detecting an amplification of 8q24 comprising contacting a chromosome sample with a labeled nucleic acid probe which binds to 8q24 . . . [and] detecting the hybridization complex." Final Office Action, page 3. The Examiner further stated: "Hainsworth teaches that, at least in some instances, there is chromosomal gain at 17q23 in primary breast cancers (see table 2, case 907, where there is a derivative of chromosome 17 which is translocated in 17q23, which represents an amplification at that position)." *Id.*

In the Amendment filed in response to the Final Office Action, Applicants argued that Hainsworth did not teach or suggest an amplification. In the Advisory Action, the Examiner accepted this argument, but nevertheless contended that the Hainsworth translocation represented a "gain" at the recited location. Advisory Action. The Examiner bases this view solely on Hainsworth's disclosure of a primary breast cancer case having a chromosome 17 abnormality denoted "der(17)t(17;?)(q23;?)." This "shorthand" would be interpreted by a cytogeneticist as describing a derivative of chromosome 17 that contained translocated chromosome 17 material

joined to an unknown chromosome. The breakpoint on chromosome 17 is q23, and the chromosome 17 material is joined to an unknown point on the other chromosome. There is simply no basis for concluding that this description suggests an increase in copy number of nucleic acid sequences at q22-q24 on chromosome 17. Thus, there is no basis for concluding that there was an amplification or gain of sequences in this region. If this rejection is maintained, Applicants respectfully request a telephonic interview.

Conclusion

In view of the foregoing, Applicants believe that all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3509.

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Respectfully submitted,

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